TITLE: Impact of Level of Effort on the Effects of Compliance with the 3-Hour Rule

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Key words: Centers for Medicare and Medicaid Services (US), propensity score, traumatic brain injuries, comparative effectiveness research, rehabilitation

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ABSTRACT

Objective: To determine if patients' level of effort (LOE) in therapy sessions during traumatic brain injury (TBI) rehabilitation modifies the effect of compliance with the 3-Hour Rule of the Centers for Medicare & Medicaid Services.

Design: Propensity score methodology applied to the TBI-Practice-Based Evidence (TBI-PBE) database, consisting of multi-site, prospective, longitudinal observational data.

Setting: Acute inpatient rehabilitation facilities (IRF).

Participants: Patients (n=1820) who received their first IRF admission for TBI in the US and were enrolled for 3 and 9 month follow-up.

Main Outcome Measures: Participation Assessment with Recombined Tools-Objective-17, FIM^{TM} Motor and Cognitive scores, Satisfaction with Life Scale, and Patient Health Questionnaire-9.

Results: When the full cohort was examined, no strong main effect of compliance with the 3-Hour Rule was identified and LOE did not modify the effect of compliance with the 3-Hour Rule. In contrast, LOE had a strong positive main effect on all outcomes, except depression. When the sample was stratified by level of disability, LOE modified the effect of compliance, particularly on the outcomes of participants with less severe disability. For these patients, providing 3 hours of therapy for 50%+ of therapy days in the context of low effort resulted in

poorer performance on select outcome measures at discharge and up to 9 months post discharge compared to patients with <50% of 3-hr therapy days.

Conclusions: LOE is an active ingredient in inpatient TBI rehabilitation, while compliance with the 3-Hour Rule was not found to have a substantive impact on the outcomes. The results support matching time in therapy during acute TBI rehabilitation to patients' LOE in order to optimize long-term benefits on outcomes.

Level of Effort Effects on 3-Hour Compliance

Key Words: Brain injuries, traumatic; Health services research; Occupational therapy; Physical therapy; Speech therapy; Recreation therapy; Rehabilitation; Therapeutics

Level of Effort Effects on 3-Hour Compliance

List of Abbreviations

ASD	Absolute standardized difference
CMS	Centers for Medicare & Medicaid Services
CSI	Comprehensive Severity Index
FIM™	Functional Independence Measure™
GPS	Generalized propensity score
IRF	Inpatient rehabilitation facility
LOE	Level of effort
LOS	Length of stay
OT	Occupational therapy
PBE	Practice-based evidence
PART-O	Participation Assessment with Recombined Tools-Objective
PHQ-9	Patient Health Questionnaire-9
POC	Point of Care
PT	Physical therapy
RITS	Rehabilitation Intensity of Therapy Scale
ST	Speech therapy
SWLS	Satisfaction with Life Scale
TBI	Traumatic brain injury
US	United States

Impact of Level of Effort on the Effects of Compliance with the 3-Hour Rule

In 1982, the Centers for Medicare & Medicaid Services (CMS) imposed a regulatory requirement on inpatient rehabilitation facilities (IRF) to provide 3 hours of therapy per day.[1] The "3-Hour Rule" mandates that to qualify for Medicare-paid IRF-level reimbursement of rehabilitation costs, IRFs must provide a minimum of 3 hours per day of either occupational therapy (OT) or physical therapy (PT) and one additional therapy, usually speech therapy (ST) for 5 of 7 days or 15 hours per week.[1] The rule is mandatory for CMS-affiliated payers, but it is not uncommon for other payers to establish similar expectations for quantity of time in therapies. Understanding whether the level of therapeutic intensity, as measured by time, is associated with the best acute inpatient rehabilitation outcomes is critical to both consumers of rehabilitation and to providers.[2,3]

The 3-Hour Rule was imposed before securing substantive evidence indicating time in therapy alone affects outcomes. An early study conducted in 1986 suggested the rule may increase costs without appreciable improvements in outcomes.[2] A Cochrane systematic review of interdisciplinary rehabilitation for stroke and traumatic brain injury (TBI) concluded there is strong evidence that more intensive treatment leads to earlier functional gains, and moderate evidence for it shortening length of stay (LOS)[3] . However, the impact on longer-term outcomes (e.g. 6-12 months post-injury) was not significant or was insufficiently studied. Also, the review was based on 4 randomized controlled trials conducted in the 1990s, in countries whose systems of care differ substantially from current rehabilitation in the United States (US), using varying definitions of treatment intensity across the studies. A more recent meta-analysis calculated a

medium effect size for intensity of rehabililitation.[4] However, the analysis included 2 of the studies from the previous systematic review and the remaining 3 were not conducted in an IRF setting or did not involve multidisciplinary rehabilitation. Two studies conducted with patients receiving stroke rehabilitation found ≥ 3 hours of therapy per day was associated with greater functional gain at discharge[5] and shorter LOS.[6] Studies varied in either collection or analysis of potential confounding variables such as age, severity, and time post-event. Despite substantial changes in rehabilitation care and payment systems, no controlled studies in the past 18 years include patients with TBI treated in US IRFs.

Recent research focuses on defining therapy intensity as a function of the complexity of therapeutic activity rather than as treatment time per se, and on identifying factors that may impact a patient's ability to participate in therapy sessions. Horn et al. found greater effort extended by TBI patients within therapy sessions and more time spent in complex therapy activities were associated with better outcomes at IRF discharge and similar, less pervasive associations at 9 months post discharge.[7] Recent research suggests the amount of effort patients are able to expend, and the content of therapy, may be the important active ingredients of rehabilitation.[8 9] For individuals with TBI, the severity of the presenting disability is an important factor influencing the ability to participate effortfully in treatment, as well as responsiveness to different therapeutic approaches.[10]

The present study is one of a series utilizing propensity score methodology to control measured confounders while evaluating rehabilitation approaches and methods of delivery. We hypothesized that patients' level of effort (LOE) during therapy sessions modifies the impact of

compliance with the 3-Hour Rule. Given that the severity of the presenting disability has been found to influence effort in treatment, we planned a priori to evaluate effect modification in groups stratified by severity in addition to the full cohort. The study provides a preliminary examination of possible causal relationships between compliance with the 3-Hour Rule, how compliance may be modified by LOE, and outcomes up to 9 months post-discharge from inpatient rehabilitation.

METHODS

This study analyzes data from the multi-site longitudinal TBI Practice-Based Evidence study that enrolled consecutive IRF admissions from 2008 to 2011 at 9 US sites and 1 in Canada.[11] The TBI-PBE Database incorporates data abstracted from medical records, Point-Of-Care (POC) documentation of IRF treatments, and follow-up interviews. During each therapy session, trained therapists using standardized POC forms recorded time in each therapeutic activity and LOE expended by the patient.

Participants. The portion of the TBI-PBE Database used in the current analysis included 1820 participants who were: aged 14 or older, received their first IRF admission for TBI rehabilitation at a US facility, consented to follow-up, received therapy after the first 3 days of the admission, and had valid LOE ratings (i.e. were not missing LOE or were not in a minimally conscious state throughout the admission). See the Participant Flow Diagram in SDC. An additional 8 participants were excluded because they did not receive weights in the propensity score model due to missing values on key variables.

Setting. The IRFs that participated in the TBI-PBE study are described by Seel et al.[12] The 9 US facilities were CMS-compliant with the 3-hour rule, typically delivering 3 hours across the 5 weekdays or delivering 15 hours across a 7-day week by exception. The mean session length was 38.6 minutes (±8.7) for PT, 37.7 (±7.7) for OT, and 32.5 (±6.1) for ST. Patients received the majority of their therapy during the week, with a median of 0.3 hours of PT and OT and 0.2 hours of ST provided on the weekend.

Severity Stratification. To evaluate heterogeneity of treatment effects, the sample was stratified into two groups based on severity of disability at admission. The Severe group consisted of patients who required maximal assistance with all self-care, mobility, and cognitive needs (FIM™ Cognitive scores at admission ≤ 15 and FIM™ Motor scores < 28.75, n=805). The Less Severe group comprised the remaining patients (n=1015).

LOE. Effort during each session was rated by the rehabilitation therapists with the Rehabilitation Intensity of Therapy Scale (RITS[8]), a single-item, behaviorally anchored, 7-point scale. Higher scores indicate more patient engagement and effort, with effort being operationally defined as being attentive and engaged in goal-directed activity, including initiating activity, incorporating therapist feedback, and persevering when therapies become challenging. [10] A number of steps were taken to minimize rater variability, bias and missing data. Therapists were trained in making RITS LOE ratings and tested twice during the study for accuracy. High accuracy rates (% correct responses) were observed at the initial testing for ST (98%), PT (97%), and OT (89%); they remained high at the 9-month follow-up test for ST (91%), PT (91%), and OT (81%).[10] The level of effort ratings across ST, PT, and OT individual therapy sessions closely

conformed to a normative distribution with minimal skewness (-.02 to -.11) and kurtosis (-.08 to -.12). Test-retest stability for the single-item level of effort ratings were excellent for all three disciplines during both morning and afternoon sessions, with intraclass correlation coefficients ranging from .76 to .80.[10] For the current study, LOE was averaged across disciplines and days of the rehabilitation stay.

Compliance with 3-Hour Rule. Hours of therapy per day were calculated from the minutes recorded on the POC forms, and used to determine the percentage of rehabilitation days in compliance with the 3-Hour Rule. (Calculation details are provided in SDC, Methodology Details). The distribution of percentage of days in compliance with the 3-Hour Rule distinguished three groups of participants: a) 3 hours or more of therapy on 50% or more of days (50%+ Compliant), b) 3 hours or more on 20-50% of days (20-50% Compliant) and c) 3 hours or more on 0-20% of days (0-20% Compliant). Percentage of therapy time in group treatment and total number of therapy hours over the entire rehabilitation stay were calculated and used in sensitivity analyses.

Outcomes. Outcome data were collected at discharge (FIM™ [13] only), and 3 and 9 months post-discharge. The primary outcome was community participation, as measured by the Participation Assessment with Recombined Tools-Objective-17 (PART-O-17).[14,15] This study used the 3 domain scores (Out and About, Social Relations, and Productivity), the Total score derived from the 3 domain scores, and a Rasch-adjusted Total score that measures participation on a ratio scale.[16] Secondary outcomes included the FIM™ Rasch-adjusted Motor and Cognitive scores,[17] Patient Health Questionnaire-9 (PHQ-9)[18] dichotomized into likely major depression versus no

major depression[19], and the Satisfaction with Life Scale (SWLS).[20] All of the measures have established psychometrics.[21-23]

Potential confounders. To ensure characteristics considered potential confounders were not impacted by the rehabilitation treatment, only variables measured at rehabilitation admission (first 3 days) or earlier were included in the propensity score adjustment model. The full list of potential confounders can be found in supplemental table S1, Balance Diagnostics.

Analysis. Data were analyzed using SAS v9.3[a] and STATA version 14.0.[b] Inverse probability weighting (IPW) with generalized propensity scores (GPS) estimated by multinomial logistic regression was used to control for measured confounders across the 3 Compliance groups. An iterative process was used to develop models that achieved the optimal balance of potential confounders, including trials of interaction terms. Balance across the three Compliance groups was assessed using the absolute standardized difference (ASD) between all possible pairs of groups[25] prior to and after weighting by the stabilized IPW. If, after IPW, the ASD for a potential confounder exceeded a conservative 0.10, the potential confounder was included as a covariate in the outcome analysis model.[25] The GPS model was estimated for the full cohort, and separately for the Severe and Less Severe subgroups.

The hypothesis that LOE would modify the effect of compliance with the 3-Hour Rule was evaluated through marginal regression models weighted by the standardized IPW, with robust sandwich standard error estimates. The potential modification by LOE of Compliance's effect on outcomes was tested first by the interaction term between LOE and Compliance (including

effects of the lower order terms), without including any covariates that were not balanced by IPW. In the second step, models were adjusted for any unbalanced covariates. Primary inference is based on and reported for the second step, because the first step was assumed to be biased by confounders. If effect modification was not significant at the $p<.05$ level, the interaction term was dropped and the main effects of Compliance and of LOE were estimated.

Sensitivity analysis evaluated the proportion of time in group therapy and total therapy hours delivered over the LOS due to concerns that these factors might influence the effects of Compliance. Multiple imputation (40 iterations) for all missing outcome measures was used to examine if findings were substantially more efficient (i.e. reduced variance) in the full sample. Heterogeneity of treatment effects in the Severe and Less Severe subgroups was evaluated by conducting analyses separately for these groups. When effects were observed in a subgroup, we compared confidence intervals of effect sizes to determine if the size of the effects differed based on severity of disability. See SDC for additional details regarding statistical methods.

RESULTS

Full cohort. The extent to which confounders were balanced across Compliance groups was evaluated by examining the ASDs for pairwise comparisons (Table 1 and supplemental table S1). Prior to weighting, mean ASD was 0.13, with a maximum of 0.84. Forty-seven percent of the confounders or levels of a confounder (for categorical variables) had ASDs greater than 0.10. The estimated stabilized IPW had an average value of 0.99 (minimum: 0.30, maximum: 17.1). After weighting, the mean ASD was reduced to 0.06 (maximum=0.13) with 4% (n=3) of the variables had ASDs exceeding the 0.10 threshold. The three unbalanced confounders

(Comprehensive Severity Index-Non-Brain Injury, premorbid alcohol misuse, private insurance) were included in the outcome analyses.

The hypothesis regarding the effect modification of LOE on compliance was tested first. Adjusting for the 3 unbalanced covariates, there was no significant effect modification between LOE and Compliance with the 3-Hour Rule for any outcome. Given that the a priori hypothesis was not supported, the interaction term was dropped and the main effects were estimated. Compliance was associated with a significantly lower PART-O Social Relations score at 3 months for those with 20-50% Compliance versus those with 50%+ Compliance (adjusted average difference: 0-20% Compliance vs. 50%+: -.08, 95% CI=-.29, .12; 20-50% Compliance vs. 50%+ Compliance: -.18, 95% CI=-.31, -.04). However, after controlling for LOE, Compliance was not strongly associated with any outcome (Table 2). LOE had a strong positive association (main effect) with all outcomes, except PHQ-9 (Table 2). These findings did not change substantially when total number of therapy hours and percentage of treatment in group therapy were added to the model, with the exception of a weaker association with SWLS at 3 months. Following multiple imputation, SWLS at 3 months was again strongly associated with LOE.

Stratification by disability severity. For the Severe subgroup, prior to weighting the mean ASD was 0.14 with a maximum of 0.75; 56% of variables had ASDs greater than 0.10. After weighting, the mean ASD was 0.10 (maximum=.0.26) with 46% of variables (36/79) had ASD exceeding 0.10. After adjustment for unbalanced covariates, significant modification of the effect of Compliance by LOE was noted for: FIM™ Cognitive at 3 months and PART-O Rasch Total

at 9 months (Table 3 and Figures 1 and 2). Post-hoc analysis of the difference in outcomes between the Compliance groups for each rating of LOE were significant for FIM Cognitive, but not for PART-O Rasch Total. Findings did not change substantially when total therapy hours and percentage of group therapy were added to the models. For those outcomes for which a significant effect modification was not found, the main effect of Compliance, adjusted for LOE, was examined. No significant main effects of Compliance were identified.

For the Less Severe subgroup, before weighting the mean ASD was 0.12 with a maximum of 0.86; 42% of the variables had ASDs > 0.10. After weighting, the mean ASD was 0.08 (maximum= 0.19) with 29% of the variables with ASDs greater than 0.10. These 23 variables were included in the adjusted outcome analysis. LOE was found to significantly modify the effect of Compliance on: PART-O Total, Total Rasch, and Social Relations at 9 months, Out and About at 3 and 9 months, Productivity at 3 months, SWLS at 3 and 9 months, and FIM™ Cognitive at discharge, after adjustment for unbalanced covariates (Table 3, Figures 3-5 and supplemental Figures S1-S5). Adding percent of group therapy and total therapy minutes to the models, the Compliance effect modification by LOE was no longer significant at the $p<.05$ level for PART-O Total Rasch at 9 months, Out and About at 3 months, and Productivity at 3 months. While effect modification of LOE remained significant for SWLS at both 3 and 9 months (Supplemental figures S4 and S5), the post-hoc comparisons at the different ratings of LOE were not significant. For those outcomes for which a significant effect modification was not found, the main effect of Compliance was examined. Adjusting for LOE, no significant main effects of Compliance were identified (Supplemental Table S2).

For both severity groups, the moderating influence of LOE on Compliance's effects was similar across the FIM™ Cognitive and PART-O outcomes, and generally in the same direction for all significant post-hoc analysis. As illustrated in Figures 1-5 (additional Figures in supplemental material), LOE had a stronger positive influence on FIM™ Cognitive and PART-O outcomes for those with 50% or more of therapy days in compliance, as compared to its influence for those in the 0-20% Compliance group. In particular for PART-O outcomes, as effort increased in those with 50% or more therapy days in compliance, outcomes improved. For those with few therapy days in compliance (0-20%) we did not see an impact on outcomes if LOE varied. The effects of LOE on the 20-50% Compliance group often fell in between the other two groups. Table 3 describes the average difference in scores, relative to 50%+ compliance, for outcomes across LOE. To determine if the size of the effects differed based on initial level of disability, we evaluated the overlap of confidence intervals for the effects. The confidence intervals of the effects overlapped substantially, suggesting that the effects of compliance and LOE on outcomes were not different between the severity groups.

DISCUSSION

Compliance with the 3-Hour Rule did not have a significant impact on outcomes in this sample of IRF patients with TBI. However, LOE was significantly associated with the majority of the outcomes up to 9 months post-discharge, including community participation, functional independence, and life satisfaction, but not likelihood of depression. Our *a priori* hypothesis that the effect of 3-Hour Rule Compliance on outcomes is moderated by the LOE that patients were able to expend in treatment was not supported when the full cohort was used in the analysis. However, when the sample was stratified by initial severity of disability, there was a significant interaction between 3-Hour Rule Compliance and LOE with regard to outcomes for patients with

less severe disability, and minimally for those with more severe disability. LOE had a stronger impact on the outcomes of those participants with 50% or more days in compliance than its impact on those with 0-20% days in compliance. Participants with lower LOE did poorly when provided with 3+ hours of therapy for more than half of their therapy days in comparison to patients who received 3+ hours of therapy during a small proportion of their rehabilitation days. Matching intensity of therapy, as measured by total time, to the patient's LOE appears to produce optimum results.

The results of this study do not support the mandate of 3 hours of therapy for all patients at all times during the inpatient stay. Rather, time in therapy needs to be tailored for each patient based on LOE, in order to maximize response to rehabilitation. This patient-centered approach is a smarter use of resources. Unfortunately, short of a reversal of a federal regulation that has been in place for over 35 years, providers will need to focus on other solutions to adapt therapy time to the patient's needs (e.g., brief frequent therapy dosing across the day, increased rest breaks, etc.) with the goal of finding the "sweet spot" between time and effort that maximizes patients' outcomes. Providers will also need to identify unique features within each individual (i.e., person-focused) to enhance LOE during therapy.

Some people might argue that persons who are only able to expend low levels of effort should be denied admission to IRFs since they do not benefit from the mandated 3 hours of therapy. This contention was not tested in our study, and we would argue against this interpretation. LOE as measured in this study was collected following admission to IRF and within the context of each

311 therapy session. The findings speak more to the need to change the therapeutic environment to
312 match patients' needs than to denying access to IRF-level of care.
313
314 This study focused on identifying what has the greatest impact on patient hospital discharge
315 outcomes and longer-term life outcomes. While time in therapy is likely to continue to be
316 debated as a potential active ingredient in inpatient rehabilitation, the current finding of the
317 importance of LOE within sessions adds to the growing body of literature indicating that time is
318 not the only ingredient to positively affect outcomes. Other studies have found that, for instance,
319 function-focused activities in rehabilitation are more effective than impairment-focused
320 activities.[9] The accumulating evidence confirms that rehabilitation is a complex process and
321 cannot be defined simply as an aggregate of time.[26] Future research must continue to focus on
322 identifying ingredients that promote the greatest benefits for patients.
323

324 **Study limitations**

325 We were not able to capture the reasons patients did not receive 3 hours of therapy, which could
326 better inform the interpretation of results. The current study based causal inference on propensity
327 score analysis of observational data, rather than on the more widely accepted randomized
328 controlled trial. We cannot be certain that all confounders were measured. In addition, while we
329 achieved excellent balance of the confounders across different levels of exposure to the treatment
330 (Compliance) for the full cohort, we were not able to achieve our pre-set criterion for a large
331 number of confounders when we stratified the sample, particularly in the Severe subgroup.
332 Adjusting the models by the unbalanced covariates increases our confidence in the results, but

interpretation still should be made cautiously. Further, while we use a comprehensive model for multiple imputation of missing outcomes, which included all covariates believed to potentially be related to outcomes, expected interactions and observed outcomes to impute missing outcomes over time, there is no test to ensure that our data was not missing due to some unobserved variables.

The associations found between LOE and the outcomes should also be interpreted carefully because the propensity score methods were used to balance the confounders on 3 Hour Rule Compliance, not on LOE. Causal inferences can only be made relative to Compliance, not LOE. The association between LOE and outcomes could be reflective of underlying factors, such as tenaciousness, that can impact performance in both rehabilitation and in the community. However, this possibility should not discount the need to adapt rehabilitation to the individual's ability to expend effort, whether this is a reflection of a temporary state or an enduring trait.

Conclusions

Engagement in therapy was found to be more important than the amount of time in therapy for optimizing outcomes, providing evidence for a need to reconsider the 3-Hour rule. Individualizing the amount of treatment per day to be in line with the person's ability to engage and fully participate in therapy will likely yield better outcomes.

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Figures

Figure 1. Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).
Figure 2: Severe subgroup: Interaction plot for FIM Cognitive Rasch at 3 months (adjusted model).

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Figure 3. Less Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).
Figure 4. Less Severe subgroup: Interaction plot for PART-O Total at 9 months (adjusted model).
Figure 5. Less Severe subgroup: Interaction plot for FIM Cognitive (Rasch) at discharge (adjusted model).

Suppliers

[a]SAS v9.3 38 (SAS Institute, Inc., Cary, NC)

[b]STATA version 14.0 39 (StataCorp, College Station, TX).

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Level of Effort Effects on 3-Hour Compliance

Table 1: Demographic and clinical characteristics at admission, by Compliance with the 3-Hour Rule exposure groups, prior to and with IPW

	Prior to IPW			With IPW			
	Compliance Group			Compliance Group			
	0-20%	20-50%	50%+	0-20%	20-50%	50%+	ASD*
Demographics							
Age at admission Mean(SD)	45.79 (20.1)	44.82 (22.0)	43.09 (21.74)	45 (21.26)	44.1 (21.58)	44.86 (21.17)	0.03
Male gender n(%)	396 (74.72)	486 (71.89)	427 (69.32)	394.64 (74.96)	493.65 (72.09)	432.08 (72.47)	0.04
Race/Ethnicity n(%)							
White non-Hispanic	380 (71.7)	508 (75.15)	490 (79.55)	384.23 (72.99)	509.34 (74.38)	454.7 (76.26)	0.05
White Hispanic	38 (7.17)	47 (6.95)	29 (4.71)	31.19 (5.93)	40.69 (5.94)	28.94 (4.85)	0.03
Black	94 (17.74)	102 (15.09)	80 (12.99)	94.26 (17.91)	114.13 (16.67)	82.68 (13.87)	0.07
Other or Unknown race/ethnicity	18 (3.4)	19 (2.81)	17 (2.76)	16.74 (3.18)	20.59 (3.01)	29.92 (5.02)	0.07
At least High school education n(%)	389 (73.4)	487 (72.04)	441 (71.59)	362.91 (68.94)	503.21 (73.49)	440.73 (73.92)	0.07
Insurance n(%)							
Private/MCO/HMO	196 (36.98)	303 (44.82)	263 (42.69)	186.03 (35.34)	286.15 (41.79)	260.9 (43.76)	0.12
Medicare	115 (21.7)	152 (22.49)	122 (19.81)	122.12 (23.2)	146.46 (21.39)	124.48 (20.88)	0.04
Medicaid	118 (22.26)	87 (12.87)	110 (17.86)	101.8 (19.34)	122.59 (17.9)	87.91 (14.74)	0.08
Self-pay/other payer	76 (14.34)	91 (13.46)	76 (12.34)	79.11 (15.03)	91.4 (13.35)	73.54 (12.33)	0.05
Workers comp	25 (4.72)	43 (6.36)	45 (7.31)	37.36 (7.1)	38.14 (5.57)	49.39 (8.28)	0.07
Premorbid Conditions							
Alcohol Misuse n(%)	259 (48.87)	215 (31.8)	177 (28.73)	199.9 (37.97)	244.93 (35.77)	176.16 (29.55)	0.12
Other drug use n(%)	159 (30)	128 (18.93)	109 (17.69)	113.46 (21.55)	152.28 (22.24)	119.86 (20.1)	0.04
Injury and status at Admission to Rehabilitation							
Cause of Injury n(%)							
Fall	169 (31.89)	208 (30.77)	189 (30.68)	178.3 (33.87)	217.91 (31.82)	177.49 (29.77)	0.06
Sports	35 (6.6)	36 (5.33)	29 (4.71)	21.49 (4.08)	35.13 (5.13)	43.29 (7.26)	0.09
Motor vehicle	279 (52.64)	380 (56.21)	374 (60.71)	278.66 (52.93)	386.31 (56.42)	339.99 (57.02)	0.05
Violence	47 (8.87)	52 (7.69)	24 (3.9)	47.98 (9.11)	45.4 (6.63)	35.46 (5.95)	0.08

Site n(%)⇞							
Site group 1	28 (5.28)	223 (32.99)	190 (30.84)	140.19 (26.63)	168.36 (24.59)	152.26 (25.54)	0.03
Site group 2	289 (54.53)	160 (23.67)	31 (5.03)	140.06 (26.61)	180.22 (26.32)	152.66 (25.61)	0.02
Site group 3	129 (24.34)	79 (11.69)	174 (28.25)	90.49 (17.19)	146.26 (21.36)	112.9 (18.94)	0.07
Site group 4	84 (15.85)	214 (31.66)	221 (35.88)	155.69 (29.57)	189.9 (27.73)	178.4 (29.92)	0.03
Time to Rehabilitation (days) Mean(SD)	24.35 (33.52)	26.2 (30.03)	28.81 (32.4)	31.15 (41.93)	27.15 (29.02)	26.17 (28.52)	0.09
FIM Motor at admission (Rasch) Mean(SD)	36.16 (16.62)	31.64 (16.76)	25.63 (17.28)	32.23 (16.11)	31.22 (17.63)	30.69 (16.22)	0.06
FIM Cognitive at admission (Rasch) Mean (SD)	39.85 (19.22)	37.89 (18.06)	30.68 (19.32)	36.55 (19.13)	35.6 (19.55)	36.42 (18.87)	0.03
Post traumatic amnesia cleared prior to rehab admission n(%)	243 (45.85)	246 (36.39)	163 (26.46)	180.29 (34.25)	245.97 (35.92)	189.52 (31.79)	0.06
CSI Brain Injury	39.11(21.12)	45.18(22.18)	53.92 (23.08)	45.35(22.28)	46.38(22.82)	46.80(22.36)	0.04
CSI Non-Brain Injury	16.34(14.76)	19.16(15.43)	17.13(14.25)	21.34(24.99)	17.43(14.55)	18.72(15.62)	0.13
Glasgow Coma Score n(%)							
Intubated/Missing	285 (53.77)	300 (44.38)	277 (44.97)	263.09 (49.98)	313.92 (45.84)	273.75 (45.91)	0.06
Mild	99 (18.68)	96 (14.2)	69 (11.2)	71.74 (13.63)	105.89 (15.46)	95.69 (16.05)	0.05
Moderate-Severe	146 (27.55)	280 (41.42)	270 (43.83)	191.6 (36.4)	264.94 (38.69)	226.79 (38.04)	0.03

* ASD of the three, two group comparisons.

⇞Site group 1 consists of sites with less than 10% of participants receiving Medicare; Site group 2 consists of sites with 10-20% of participants receiving Medicare; Site group 3 consists of sites with 20-30% of participants receiving Medicare and Site group 4 consists of sites with >30% receiving Medicare

Table 2: Full cohort, adjusted main effects of LOE and Compliance with the 3-Hour Rule, (*average adjusted effect, 95% confidence interval)*

Outcome	Time Point	LOE** (adjusted for Compliance)	Compliance Group	Compliance** (adjusted for LOE)
PART-O Total	3 months	0.25 (0.21, 0.30)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.2 (-0.12, 0.09) -0.02 (-0.11, 0.07)
	9 months	0.26 (0.20, 0.32)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.04 (-0.19, 0.10) -0.02 (-0.12, 0.09)
PART-O Rasch Total	3 months	4.31 (3.39, 5.23)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.82 (-2.29, 0.65) -0.94 (-2.37, 0.49)
	9 months	3.57 (2.58, 4.56)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.08 (-1.86, 2.03) 0.00 (-1.49, 1.49)
PART-O Social	3 months	0.24 (0.15, 0.32)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.03 (-0.22, 0.15) -0.15 (-0.28, -0.02)
	9 months	0.21 (0.13, 0.28)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.09 (-0.26, 0.09) -0.06 (-0.18, 0.06)
PART-O Productivity	3 months	0.29 (0.24, 0.34)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.02 (-0.11, 0.15) 0.09 (-0.03, 0.20)
	9 months	0.36 (0.30, 0.43)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.01 (-0.18, 0.20) 0.01 (-0.14, 0.17)
PART-O Out and About	3 months	0.23 (0.17, 0.29)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.04 (-0.19, 0.12) -0.01 (-0.13, 0.12)
	9 months	0.21 (0.14, 0.27)‡	0-20% vs. >=50% 20-50% vx. >=50%	-0.05 (-0.23, 0.14) 0.02 (-0.11, 0.15)
FIM Rasch Cognitive	Discharge	11.42 (10.55, 12.30)‡	0-20% vs. >=50% 20-50% vx. >=50%	1.18 (-0.86, 3.22) 0.38 (-1.29, 2.06)
	3 months	8.69 (6.87, 10.50)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.88 (-2.66, 4.43) -0.94 (-4.06, 2.18)
	9 months	7.55 (5.56, 9.54)‡	0-20% vs. >=50% 20-50% vx. >=50%	1.08 (-2.69, 4.85) 0.63 (-1.91, 3.16)

FIM Rasch Motor	Discharge	8.52 (7.40, 9.63)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.81 (-1.05, 2.66) 0.86 (-0.65, 2.37)
	3 months	11.02 (9.11, 12.93)‡	0-20% vs. >=50% 20-50% vx. >=50%	1.35 (-2.61, 5.31) 1.85 (-1.01, 4.70)
	9 months	9.73 (7.34, 12.12)‡	0-20% vs. >=50% 20-50% vx. >=50%	0.14 (-4.34, 4.62) -0.35 (-3.23, 2.53)
Satisfaction with Life	3 months	0.77 (0.09, 1.44)*	0-20% vs. >=50% 20-50% vx. >=50%	0.21 (-1.73, 2.14) -0.31 (-1.80, 1.18)
	9 months	1.25 (0.48, 2.02)†	0-20% vs. >=50% 20-50% vx. >=50%	-0.42 (-2.63, 1.78) 0.56 (-0.85, 1.97)
PHQ-9	3 months	1.13 (0.89, 1.43)	0-20% vs. >=50% 20-50% vx. >=50%	0.71 (0.38, 1.31) 0.65 (0.40, 1.05)
	9 months	0.99 (0.80, 1.23)	0-20% vs. >=50% 20-50% vx. >=50%	1.16 (0.66, 2.05) 0.68 (0.42, 1.08)

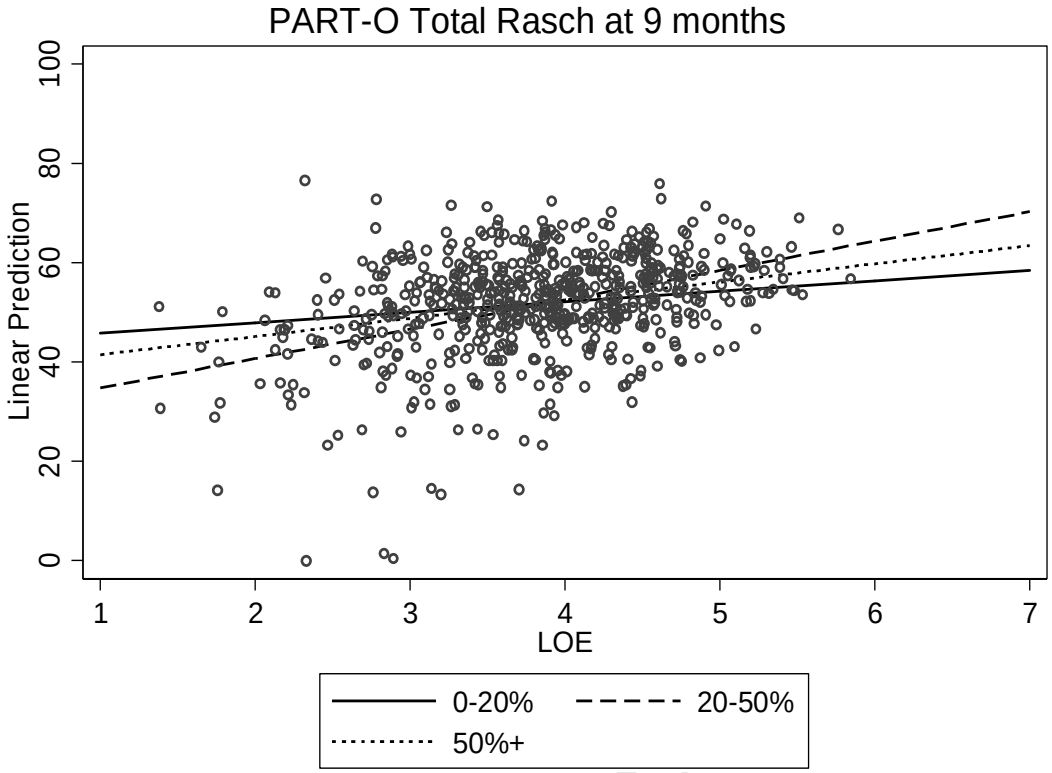
** Mean differences (95% Confidence Intervals) for all outcomes except PHQ-9, which is an Odds Ratio

* $p<.05$; † $p<.01$; ‡ $p<.001$

Table 3: Subgroup adjusted, significant (p<.05) effect modification (mean differences) of LOE on Compliance with the 3-Hour Rule, by LOE (*average adjusted effect (95% confidence interval)*

Outcome	**Compliance group**	**LOE: 1↟**	**LOE: 4**	**LOE: 7**
Severe Cohort				
PART-O Total Rasch, 9 months				
	0-20% vs. 50% +	4.34 (-2.38, 11.06)	-0.33 (-3.02, 2.37)	-4.99 (-13.64, 3.66)
	20-50% vs. 50% +	-6.71 (-14.77, 1.35)	0.05 (-1.55, 1.65)	6.82 (-0.97, 14.61)
FIM Rasch Cognitive, 3 months				
	0-20% vs. 50% +	25.66 (10.63, 40.69)	-0.58 (-4.87, 3.71)	-26.82 (-44.17, -9.47)
	20-50% vs. 50% +	-1.65 (-17.32, 14.01)	0.72 (-2.72, 4.17)	3.1 (-14.42, 20.63)
Less Severe Cohort				
PART-O Total, 9 months				
	0-20% vs. 50% +	0.99 (0.37, 1.61)	0.24 (0.06, 0.42)	-0.51 (-0.92, -0.1)
	20-50% vs. 50% +	0.62 (-0.02, 1.27)	0.15 (-0.03, 0.33)	-0.32 (-0.72, 0.08)
PART-O Total Rasch, 9 months				
	0-20% vs. 50% +	11.71 (4.27, 19.15)	3.74 (1.66, 5.82)	-4.23 (-9.24, 0.78)
	20-50% vs. 50% +	7.07 (-0.95, 15.08)	2.62 (0.45, 4.79)	-1.83 (-7.1, 3.45)
PART-O Out and About, 3 months				
	0-20% vs. 50% +	1.06 (0.12, 2)	0.18 (-0.07, 0.44)	-0.7 (-1.27, -0.12)
	20-50% vs. 50% +	0.36 (-0.5, 1.23)	0.05 (-0.19, 0.28)	-0.27 (-0.81, 0.27)
PART-O Out and About, 9 months				
	0-20% vs. 50% +	1.12 (0.39, 1.86)	0.31 (0.1, 0.52)	-0.51 (-0.99, -0.02)
	20-50% vs. 50% +	0.9 (0.15, 1.65)	0.27 (0.06, 0.47)	-0.37 (-0.86, 0.13)
PART-O Productivity, 3 months				
	0-20% vs. 50% +	1.17 (0.28, 2.07)	0.27 (0.07, 0.48)	-0.63 (-1.28, 0.03)
	20-50% vs. 50% +	0.7 (-0.21, 1.61)	0.26 (0.06, 0.46)	-0.18 (-0.84, 0.48)
PART-O Social, 9 months				
	0-20% vs. 50% +	1.37 (0.57, 2.17)	0.28 (0.05, 0.51)	-0.81 (-1.32, -0.3)
	20-50% vs. 50% +	0.81 (-0.06, 1.69)	0.13 (-0.12, 0.38)	-0.56 (-1.08, -0.03)
FIM Rasch Cognitive, Discharge				
	0-20% vs. 50% +	12.56 (2.07, 23.05)	3.68 (1.06, 6.3)	-5.21 (-12.26, 1.85)
	20-50% vs. 50% +	-0.55 (-12.12, 11.01)	0.51 (-2.11, 3.12)	1.57 (-6.35, 9.48)
Satisfaction with Life, 9 months				
	0-20% vs. 50% +	8.66 (-2.64, 19.95)	1.98 (-1.23, 5.19)	-4.7 (-11.16, 1.77)
	20-50% vs. 50% +	-0.97 (-12.79, 10.84)	1.04 (-2.2, 4.27)	3.05 (-3.54, 9.63)
Satisfaction with Life, 3 months				
	0-20% vs. 50% +	7.06 (-1.53, 15.65)	1.27 (-1.43, 3.97)	-4.52 (-9.75, 0.7)
	20-50% vs. 50% +	-5.49 (-14.08, 3.1)	-1.41 (-4.1, 1.28)	2.68 (-2.04, 7.39)

↟ LOE=2,3,5,6 are excluded from table for readability, see figures for all values.



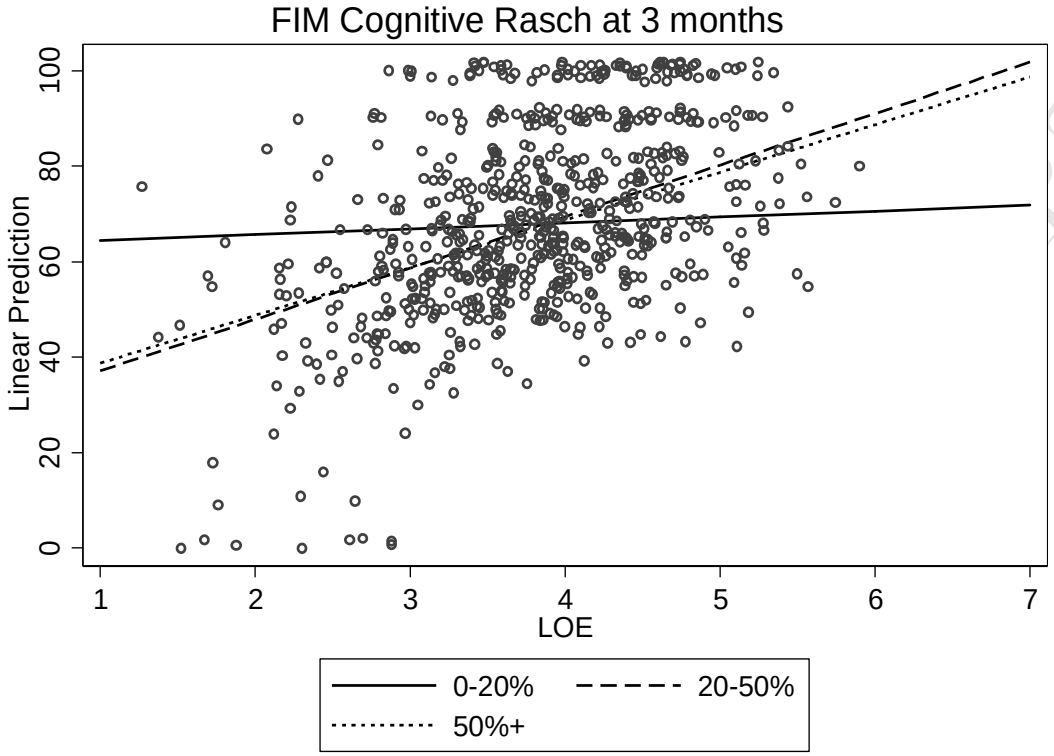


Figure 3. Less Severe subgroup: Interaction plot for PART-O Total Rasch at 9 months (adjusted model).